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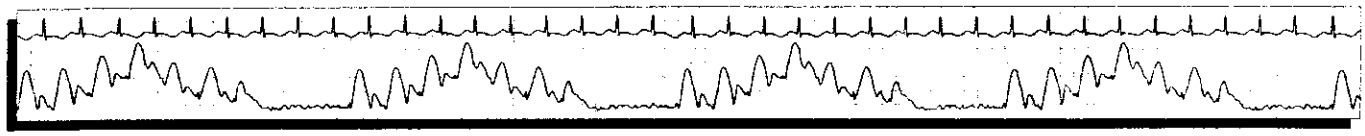
ADVANTAGE MEDICAL

Electronics, Inc.



510(K) SUMMARY

MAR 2 0 2007

Submitter Information

Name: Advantage Medical Cables, Inc.
10630 Wiles Road
Coral Springs, Florida 33076 USA

Phone: 954-345-9800
Fax: 954-345-0507
Web: www.advantagemed.com

Contact: Ken Kendricks Extension 1012
kenk@advantagemed.com

Date prepared: December 18, 2006

Name of Device

Trade Name: Advantage Cuff
NIBP Hose
NIBP Adapter

Common Name: Non-invasive Blood Pressure Cuff
NIBP Hose
NIBP Adapter

Classification Name: Cuff, Blood Pressure, DXQ, 870.1120
Class II Device
NIBP Hoses and Adapters are not classified,
Classified same as BP cuff by default.

Legally marketed predicated device

AMC has identified a legally marketed predicated device of substantial equivalence to the Advantage Cuff, NIBP Hose and Adapter.

Sensa®-Cuff, produced by GE® Medical Systems, 510(k) K022482. See Attachment 1.

GE® Medical Systems Hose "Spare Parts".

GE® Medical Systems, Critikon® Adapters, REF: 330084.

No 510(k) numbers are listed for hoses and adapters.

Description

The Advantage Cuff, NIBP Hose and Adapters are accessories for noninvasive blood pressure systems.

Cuff: The cuff is comprised of an air tight bladder enclosed in an inelastic sleeve with one or two tubes and the appropriate connectors for the type device required. The Advantage Cuffs come in a range of sizes, each marked with the appropriate limb circumference for which the cuff is intended.

Hose: The hose is comprised of single or dual tubing, in various lengths as required by the customer or application, with the appropriate connectors attached to each end of the tubing.

Adapters: The adapters are comprised of short pieces of tubing in a "Y" configuration primarily to adapt a single tube cuff to a dual tube hose or a dual tube cuff to a single tube hose as required by the customer.

Intended Use

The Advantage Cuff is an accessory that is intended to be used with manual or automated noninvasive sphygmomanometers. The cuff makes no diagnosis. The cuffs are provided non-sterile and may be reused. The cuff is not designed, sold or intended for use except as indicated.

The NIBP Hose and Adapters are accessories that are intended to be used with manual or automated noninvasive sphygmomanometers. They make no diagnosis. The hoses and adapters are provided non-sterile and may be reused. The hose and adapters are not designed, sold or intended for use except as indicated.

Comparison of Predicated Devices

The Advantage Cuffs, NIBP Hoses and Adapters have the same basic construction as the predicated devices. Both devices are wrapped the patients arm or leg and secured by a hook and loop fastener commonly called Velcro. Both devices are available in the same size and range and are intended for the same patient populations.

Testing

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The Advantage Cuffs were tested according to the applicable sections of the following standards:

AAMI SP-10:2002 & 2002/A1:2003 Manual, electronic or automated Sphygmomanometers
BS EN 1060 Non-Invasive Sphygmomanometers
ISO 10993 Biological Evaluation of Medical Devices

Conclusion

The Advantage Cuff is equivalent in safety and usage to the legally marketed predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2007

Advantage Medical Cables, Inc.
c/o Mr. Kenneth E. Kendricks
Vice President
10630 Wiles Road
Coral Springs, Florida 33076

Re: K063863
Trade Name: Advantage Cuff, NIBP Hose, and NIBP Adapter
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: December 22, 2006
Received: December 28, 2006

Dear Mr. Kendricks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K063863

Device Name: Advantage Cuff, NIBP Hose and NIBP Adapter

Indications For Use:

AMC replacement non-invasive blood pressure cuffs, interface hoses and adapters are accessories for noninvasive blood pressure systems with manual or automated noninvasive sphygmomanometers. The cuffs, interface hoses and adapters are supplied non-sterile and may be reused. The NIBP Cuffs and interface cables are supplied in adult, pediatric, infant and neonatal sizes. The cuffs, interface hoses and adapters are not designed, sold or intended for use except as indicated.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063863